

<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional)  PAT051825-US-PCT	
	Application Number  10/574,437	Filed  (Intl.) October 4, 2004	
	First Named Inventor Paolo COSTANTINO et al.		
	Art Unit  1645	Examiner  P. A. Duffy	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s).          Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="width: 60%;"> <p><input type="checkbox"/> applicant /inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input type="checkbox"/> attorney or agent of record. Registration number _____</p> <p><input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. <u>48,751</u></p> </div> <div style="width: 35%; text-align: center;"> <p>_____ /Otis Littlefield/ Signature</p> <p>_____ Otis B. Littlefield Typed or printed name</p> <p>_____ 415.268.6846 Telephone number</p> <p>_____ January 17, 2012 Date</p> </div> </div> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			
<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.			

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Paolo COSTANTINO et al.

Application No.: 10/574,437

Confirmation No.: 9723

Filed: (Intl.) October 4, 2004

Art Unit: 1645

For: HYPO- AND HYPER-ACETYLATED  
MENINGOCOCCAL CAPSULAR  
SACCHARIDES

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Examiner: P. A. Duffy

**ARGUMENTS ACCOMPANYING PRE-APPEAL BRIEF REQUEST FOR REVIEW**

MAIL STOP: AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**REMARKS**

The following arguments are presented in support of the Pre-appeal Brief Request for Review being filed concurrently with a Notice of Appeal.

Claims 1-9, 11-23, 25 and 27 are pending. Claims 10, 24, and 26 are canceled. Claims 2, 9, 25, and 27 are withdrawn. Therefore, claims 1, 3-8, and 11-23 are under examination.

**I. Double Patenting**

Claims 1, 3-8, 11-13 and 14-18 and 20-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-33 of copending Application No. 12/351,281, claims 24-44 of copending Application No. 12/321,464, and claims 34 and 67 of copending Application No. 12/321,420.

Applicants note that if the only rejections pending in an earlier filed application such as the present application are provisional double patenting rejections over later filed applications such as those referenced above, the Examiner should withdraw the provisional rejections and allow the earlier filed application to issue. *See* MPEP 804(I)(B)(1). Thus, since Applicants have addressed the only other remaining rejections below, Applicants respectfully request that these provisional rejections be withdrawn and the application proceed to allowance.

## **II. Claim Rejection Under 35 USC §102(b)**

Claims 1, 3-8, 11-18 and 20-23 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by WO 03/007985.

Applicants respectfully traverse the rejection and its supporting remarks. WO03/007985 fails to anticipate the pending claims as it fails to teach either expressly or inherently that the saccharides have “between 2-9% of the sialic acid residues in the saccharide are O-acetylated at the 7 position” and/or “between 35-55% of the sialic acid residues in the saccharide are O-acetylated at the 9 position”. The Examiner has acknowledged that WO03/007985 fails to expressly disclose either claim limitation. The Examiner instead appears to be asserting that WO03/007985 inherently discloses capsular saccharides that meet these limitations based upon the assertion that “As the instantly claimed conjugates are made by the identical process as the prior art, the compositions of the prior art necessarily have the recited structures present and uses the same strain W135 see data at pages 20 and 27.” Applicants respectfully disagree with the Examiner’s assertion and characterization of the teachings of WO03/007985. First, the two pages of WO03/007985 cited by the Examiner only have tables that indicate the immune response against reference strains, not the source strains used to make the capsular polysaccharide conjugates. Page 19, lines 10-15 of WO03/007985 teaches that the tables show the bactericidal activity against the two MenW135 test strains. MenW135 5554 was selected because it was an O-acetylation positive strain (OAc+) and MenW135 242317 was selected because it was an O-acetylation negative strain (OAc-). Thus, this section clearly teaches that there are MenW strains that have O-acetylation and MenW strains that do not have O-acetylation. Thus, WO03/007985 does not teach the strain of MenW that was used to generate the capsular saccharide. Since WO03/007985 does not teach which strain was used in the protocols on pages 16-17, WO03/007985 does not *necessarily* teach MenW compositions that

would inherently meet the limitations of the pending claims. MPEP 2112(IV) sets out the requirements for inherent anticipation as:

The fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, *may not be established by probabilities or possibilities*. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) ...

If one of skill in the art used the methods of WO03/007985 on an OAc- strain such as MenW 242317, the resulting capsular saccharides would likely not meet the limitations of the claim. Therefore, based upon starting materials having a different degree of starting O-acetylation alone, WO03/007985 does not inherently anticipate the pending claims. Moreover, the burden to establish inherency is clearly on the Examiner. The Examiner cannot merely assert that inherency is found absent evidence to the contrary. Thus, unless the Examiner can provide evidence or sound reasoning that WO03/007985 *necessarily* teaches capsular saccharides meeting the limitations of the claims, the Examiner has not established that WO03/007985 inherently anticipates the claimed invention.

Furthermore, the Examiner cannot rely upon shifting the burden to Applicants to prove that the prior art does not inherently teach the limitations of the claimed invention. That principle appears in MPEP 2112(V), i.e., in the sub-section following the above quoted text clearly establishing that the Examiner must first meet the burden of teaching that WO03/007985 *necessarily* teaches capsular saccharides meeting the limitations of the claims as provided in MPEP 2112(IV). Only after the Examiner has met that burden does the burden shift to Applicants to prove otherwise.

In addition, the Examiner's assertion that "The skilled artisan would necessarily recognize that the conjugated immunogen [in WO03/007985] necessarily is from the W135 5554 strain" finds no support in WO03/007985. WO03/007985 teaches on page 27 that the vaccine actually produced a higher serum bactericidal titre against the MenW 242317 strain (which as discussed above would likely not meet the pending claim limitations). Therefore, one of skill in the art could be more likely to assume that the starting strain was MenW 242317, in which case WO03/007985 would not anticipate the pending claims. Applicants therefore respectfully request the withdrawal of the rejection of claims 1, 3-8, 11-13 and 14-18 and 20-23.

### **III. Claim Rejections Under 35 USC §102**

Claims 1, 3-8, 11-18 and 20-23 stand rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Costantino (U.S. Publication No. 2009/0117148) or Costantino U.S. Publication No. 2009/0182129) or Costantino (U.S. Publication No. 2009/0130147) or Costantino (U.S. Publication No. 2005/0106181).

Applicants respectfully traverse the rejection and its supporting remarks. All four of the cited patent applications claim priority to WO03/007985 discussed above, as a national phase or as continuations or divisionals thereto. The Examiner has not cited to any alleged differences in the disclosures of these US patent publications compared to WO 03/007985. Therefore, as discussed above regarding WO03/007985, all of the cited patent applications also fail to anticipate the pending claims as each fails to teach either expressly or inherently that the saccharides have "between 2-9% of the sialic acid residues in the saccharide are O-acetylated at the 7 position" and/or "between 35-55% of the sialic acid residues in the saccharide are O-acetylated at the 9 position". Applicants therefore respectfully request the withdrawal of the rejection of claims 1, 3-8, 11-18 and 20-23.

### **IV. Claim Rejections Under 35 USC §103**

Claim 19 stands rejected under 35 U.S.C. 103(a) as being unpatentable over WO 03/007985 published 30 January 2003 in view of WO 03/080678, published October 2, 2003, filed March 23, 2003) for reasons made of record in the Office Action mailed April 21, 2011.

Applicants respectfully traverse the rejection and its supporting remarks. As discussed above, WO03/007985 fails to teach or suggest either expressly or inherently that the saccharides

have “between 2-9% of the sialic acid residues in the saccharide are O-acetylated at the 7 position” and/or “between 35-55% of the sialic acid residues in the saccharide are O-acetylated at the 9 position” for the reasons discussed in Section II, above. Therefore, the Examiner has not established a *prima facie* case of obviousness. Applicants therefore respectfully request the withdrawal of the rejection of claims 1, 3-8, 11-13 and 14-18 and 20-23.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 223002121500**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: January 17, 2012

Respectfully submitted,

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